REMARKS

Claims 11-12 and 17 are all the claims pending in the application.

Claims 11-12 and 17 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Tanaka et al. in view of Garvey et al. as evidenced by Mesh Supplementary Data and further in view of Guittard et al. and Sigurdsson (US 6,132,365).

Tanaka et al, Garvey et al., Mesh Supplementary Data and Guittard et al. are relied on as in the previous Actions.

Sigurdsson is newly cited as teaching that urinary incontinence is caused by unstable bladder (column 1, lines 34-36).

According to the Examiner, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references so as to administer silodosin (alpha-adrenoreceptor antagonist) in combination with ethyl(-)-24442-[[(1S,2R)-2-hydroxy-2-(4- hydroxypheny1)-1-ethylethyl]amino] ethyl] -2,5-dimethylphenoxy]acetate in view of teachings of Tanaka et al and Garvey et al. It is the Examiner's position that one would have been motivated to do so because each of the therapeutics have been taught in the prior art to be useful for the treatment of urinary incontinence. Further, the Examiner asserts Guittard et al. teaches that urinary incontinence is alternatively known as an overactive bladder. Additionally, the Examiner states that urinary incontinence is known to be associated with unstable bladder, per Sigurdsson.

Thus, the Examiner concludes that the idea of combining administration of the two agents flows logically from their having been taught in the prior art and that one of ordinary skill in the art would have had a reasonable expectation of success that administration of both agents would be useful for the treatment of urinary incontinence.

Applicants respectfully traverse the rejection.

The Examiner essentially maintains the obviousness rejection for the reasons of record and additionally based on the teaching of Sigurdsson that urinary incontinence is caused by involuntary contractions of the bladder muscle, i.e., unstable bladder. However, the addition of Sigurdsson does not remedy the deficiencies of the previously cited references as discussed in the Remarks of the Amendment filed November 24, 2010.

Specifically, (1) the teachings of Tanaka and Garvey et al do not provide a reason to a person having ordinary skill in the art to use silodosin alone or in combination with a phenoxyacetic acid derivative (I) of the presently claimed invention for treating urinary frequency or incontinence accompanied with neurogenic bladder dysfunction, unstable bladder, bladder spasm, chronic or acute cystitis or chronic or acute prostatitis as recited in the present claims; and (2) the unexpected results obtained by the presently claimed invention rebut any prima facie case of obviousness that may have been set forth.

As pointed out in the Remarks of the Amendment filed November 24, 2010, the teachings of Tanaka and Garvey et al. do not provide a reason to a person having ordinary skill in the art to use silodosin in combination with a phenoxyacetic acid derivative (I) of the presently claimed invention for treating urinary frequency or incontinence accompanied with neurogenic bladder dysfunction, unstable bladder, bladder spasm, chronic or acute cystitis or chronic or acute prostatitis.

Garvey et al. relates to a composition and method for treating overactive bladder comprising administering a compound of claim 1, at least one compound that donates nitric oxide or the like (claim 17) and further at least one vasoactive agent (at least three compounds). Thus, the composition and method of Garvey are different from the claimed invention and one of

ordinary skill in the art would not have been motivated to modify or combine the teachings of Garvey et al and Tanaka to arrive at the claimed invention. Sigurdsson does not remedy this deficiency or teach anything that would motivate one of ordinary skill in the art to modify the combination or method of Tanaka and Garvey et al., even if combined, to arrive at the claimed invention.

Garvey et al. mentions urge incontinence and overactive bladder as conditions that may be treated, however, there is no example of such treatment and no guidance or suggestion as to which of the many potential combinations of agents suggested might have been considered for the treatment of these particular conditions amongst all of the conditions listed. There is no data supporting the effect of such a combination with respect to overactive bladder. Thus, one of ordinary skill in the art would not have been motivated to use silodosin for the treatment of urinary frequency or incontinence with a reasonable expectation of success based on the teachings of Tanaka and Garvey et al. Sigurdsson does not remedy this deficiency or teach anything that would motivate one of ordinary skill in the art to modify the combination or method of Tanaka and Garvey et al., even if combined.

Mesh Supplementary Data is relied on as teaching that KMD-3213 is an alternative name for silodosin, which is not disputed.

The Examiner relies on Guittard et al primarily for the teaching of a relationship between urge incontinence and overactive bladder. However, Applicants submit that the teaching by Guittard et al that "involuntary urinary incontinence is also known as urge incontinence and overactive bladder" is incorrect. Urinary incontinence and overactive bladder are not the same.

Sigurdsson merely states that urinary incontinence is caused either by involuntary muscle contractions of the bladder muscle (so called unstable bladder) or by insufficient contraction of

the urethral sphincter muscle. Sigurdsson also teaches that unstable bladder can be treated with medication or bladder training. Column 1, lines 38-39. However, that fact that urinary incontinence may be caused by unstable bladder or may be treated with medication is not in dispute. Moreover, the teachings of Sigurdsson do not add anything to the other cited references which might motivate one of ordinary skill in the art to modify or combine the references and employ the specifically claimed combination of silodosin and a phenoxyacetic acid derivative of formula (I) of the presently claimed invention for treating urinary frequency or incontinence accompanied with neurogenic bladder dysfunction, unstable bladder, bladder spasm, chronic or acute cystitis or chronic or acute prostatitis.

Even further, Sigurdsson is related to a non-pharmacological approach to urinary incontinence caused by a weak or damaged sphincter muscle, which is not related to the present invention or any other pharmacological treatment methods at all.

Moreover, Sigurdsson does not provide any teachings or disclosure to refute Applicants' evidence of unexpected results regarding the present invention. As previously pointed out, the results in the specification show the direct effect of improvement of urinary frequency of silodosin, not a secondary effect by inhibiting contraction of urethra. Sigurdsson is not at all related to a pharmacological method of treatment and does not refute Applicants' evidence of unexpectedly superior results.

In view of the above, the present invention is not rendered obvious by the cited references, whether taken alone or in combination. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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